



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption Applications;
Extending the Duration of the Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program to May 8, 2014, for sponsors who have already been accepted for the program.

DATES: This notice is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

In the Federal Register of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled “Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.” This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Concurrent with the publication of the draft guidance, FDA also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152; November 10, 2011) intended to collect information and experience on the application of the draft guidance in order to inform the final guidance document.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012, and stated that the pilot program would terminate on May 8, 2012. In the Federal Register notice announcing the pilot program, FDA also stated its intention to limit the pilot program to nine candidates.

FDA began accepting nominations for the pilot program on December 12, 2011. After reviewing the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program. In the Federal Register of March 6, 2012 (77 FR 13343), FDA terminated the acceptance of applications into the program and extended the pilot program for the nine accepted sponsors until May 8, 2013. The pilot program will be further extended for the nine accepted sponsors until May 8, 2014.

Dated: April 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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